

**DETAILED ACTION**

**EXAMINER'S AMENDMENT**

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 22 February 2010, Michael Conger, Reg. No. 43,562 authorized the Director to charge Deposit Account No. 07-1392 the required fee for this extension and authorized the following examiner's amendment. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Michael Conger, Reg. No. 43,562 on 22 February 2010.

The application has been amended as follows:

**IN THE CLAIMS:**

Claim 1. (Currently Amended) A method for preserving an active agent comprising the steps of:

- a) preparing a preservation sample by dissolving or suspending active agent in a solution of a stabilizing agent comprising a polyol at a concentration of between ~~14%~~ 3.15% and 50% (w/v);

b) subjecting the preservation sample to temperate and pressure conditions such that the preservation sample loses solvent by evaporation without freezing or bubbling, thereby forming a viscous liquid, wherein the active agent retains at least 40% of the antigenicity, activity, immunogenicity, or combination thereof, as compared to a reference sample that has not been subject to the evaporation process.

Claim 41. (Currently Amended) The method of claim 1, wherein the stabilizing agent is present at a concentration of between ~~2%~~ 3.15% and 25% (w/v).

1. Claims 1-41 are pending and under consideration.

#### **Rejections Withdrawn**

2. The rejection of claims 1-13 and 15-41 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all concentration of stabilizing agent less than 3.15% w/v, is withdrawn in light of the amendment of the claims.
3. The rejection of claim 14 under 35 U.S.C., second paragraph, indefiniteness, is withdrawn in light of the claim amendments.
4. The provisional rejection of claims 23-33 and 36-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-3, 6, 14-18 and 20 of copending Application No. 10/533,464 is withdrawn as this is the sole remaining rejection.

#### **Conclusion**

5. Claims 1-41 are allowed.
6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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/Rodney P. Swartz, Ph.D./  
Primary Examiner, Art Unit 1645  
February 25, 2010